

EXHIBIT 12

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HEADLINE: DRUG FILES SHOW MAKER PROMOTED UNAPPROVED USE

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BODY:

Eli Lilly encouraged primary care physicians to use Zyprexa, a powerful drug for schizophrenia and bipolar disorder, in patients who did not have either condition, according to internal Lilly marketing materials.

The marketing documents, given to The New York Times by a lawyer representing mentally ill patients, detail a multiyear promotional campaign that Lilly began in Orlando, Fla., in late 2000. In the campaign, called Viva Zyprexa, Lilly told its sales representatives to suggest that doctors prescribe Zyprexa to older patients with symptoms of dementia.

A Lilly executive said that she could not comment on specific documents but that the company had never promoted Zyprexa for off-label uses and that it always showed the marketing materials used by its sales representatives to the Food and Drug Administration, as required by law.

"We have extensive training for sales reps to assure that they provide information to the doctors that's within the scope of the prescribing information approved by the F.D.A.," Anne Nobles, Lilly's vice president for corporate affairs, said in an interview yesterday.

Zyprexa is not approved to treat dementia or dementia-related psychosis, and in fact carries a prominent warning from the F.D.A. that it increases the risk of death in older patients with dementia-related psychosis. Federal laws bar drug makers from promoting prescription drugs for conditions for which they have not been approved -- a practice known as off-label prescription -- although doctors can prescribe drugs to any patient they wish.

Yet in 1999 and 2000 Lilly considered ways to convince primary care doctors that they should use Zyprexa on their patients. In one document, an unnamed Lilly marketing executive wrote that these doctors "do treat dementia" but "do not treat bipolar; schizophrenia is handled by psychiatrists."

As a result, "dementia should be first message," of a campaign to primary doctors, according to the document, which appears to be part of a larger marketing presentation but is not marked more specifically.

Later, the same document says that some primary care doctors "might prescribe outside of label."

Ms. Nobles said that the company had never promoted its drug for any conditions except schizophrenia and bipolar disorder. Older patients who seem to have dementia may actually have schizophrenia that has gone untreated,

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Ms. Nobles said.

Several psychiatrists outside the company said yesterday that they strongly disagreed with Lilly's claim. Schizophrenia is a severe disease that is almost always diagnosed when patients are in their teens or 20s. Its symptoms could not be confused with mild dementia, these doctors said.

Zyprexa is by far Lilly's best-selling product, with \$4.2 billion in sales in 2005, 30 percent of its overall revenues. About two million people worldwide received it last year. Based in Indianapolis, Lilly is the sixth-largest American drug company.

The issue of off-label marketing is controversial in the drug industry. Nearly every company is under either civil or criminal investigation for alleged efforts to expand the use of its drugs beyond the specific illness or condition for which they are approved.

Lilly faces federal and state investigations over its marketing of Zyprexa. In its annual report for 2005, Lilly said that it faced an investigation by federal prosecutors in Pennsylvania and that the Florida attorney general's office had subpoenaed the company "seeking production of documents relating to sales of Zyprexa and our marketing and promotional practices with respect to Zyprexa."

Since Lilly introduced Zyprexa in 1996, about 20 million patients worldwide have received the drug, which helps control the hallucinations and delusions associated with schizophrenia and severe mania. But Zyprexa also causes weight gain in many patients, and the American Diabetes Association found in 2004 that Zyprexa was more likely to cause diabetes than other widely used drugs for schizophrenia.

Lilly says that no link between Zyprexa and diabetes has been proven.

As part of the "Viva Zyprexa" campaign, in packets for its sales representatives, Eli Lilly created the profiles of patients whom it said would be suitable candidates for Zyprexa. Representatives were told to discuss the patient profiles with doctors. One of the patients was a woman in her 20s who showed mild symptoms of schizophrenia, while another was a man in his 40s who appeared to have bipolar disorder.

The third patient was "Martha," a widow with adult children "who lives independently and has been your patient for some time." Martha was described as being agitated and having disturbed sleep, but without the symptoms of paranoia or mania that typically marked a person with schizophrenia or bipolar disorder.

Ms. Nobles said that Lilly had actually intended Martha's profile to represent a patient with schizophrenia. But psychiatrists outside the company said this claim defied credibility, especially given Martha's age. Instead, she appeared to have mild dementia, they said.

"It'd be very unusual for this to be a schizophrenic patient," said Dr. John March, chief of child and adolescent psychiatry at Duke University medical center. "Schizophrenia is a disease of teenagers and young adults." Dr. March serves on Lilly's scientific advisory board.

Diagnostic criteria for schizophrenia include delusions, hallucinations, disorganized and incoherent speech, and grossly disorganized behavior. They also include so-called negative symptoms like social isolation and a flattening of the voice and facial expressions.

The documents also show that Lilly encouraged primary care doctors to treat the symptoms and behaviors of schizophrenia and bipolar disorder even if the doctors had not actually diagnosed those diseases in their patients. Lilly's market research had found that many primary care doctors did not consider themselves qualified to treat people with schizophrenia or severe bipolar disorder.

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The campaign was successful, the documents show. By March 2001, about three months after the start of Viva Zyprexa, the campaign had led to 49,000 new prescriptions, according to a presentation that Michael Bandick, the brand manager for Zyprexa, gave at a national meeting of Lilly sales representatives in Dallas. Mr. Bandick did not say how many of those new prescriptions were for older patients with dementia.

Over all, sales of Zyprexa doubled between 1999 and 2002, rising from \$1.5 billion to \$3 billion in the United States. In 2002, the company changed the name of the primary care campaign to "Zyprexa Limitless" and began to focus on people with mild bipolar disorder who had previously been diagnosed as depressed -- even though Zyprexa has been approved only for the treatment of mania in bipolar disorder, not depression.

In a 2002 guide for representatives, Lilly presented the profile of "Donna," a single mother in her mid-30s whose "chief complaint is, 'I feel so anxious and irritable lately.'" Several doctors' appointments earlier, she was "talkative, elated, and reported little need for sleep."

Lilly's efforts to promote Zyprexa to primary care doctors disturbed some physicians, the documents show. In August 2001, a doctor in Virginia sent an e-mail message to Lilly and the F.D.A., complaining about a presentation from a Lilly sales representative who had discussed the hypothetical Martha with him.

The representative "presented an elderly female patient who was presented to her physician by her family complaining of insomnia, agitation, slight confusion, and had no physical finding to explain her state," the doctor wrote. The representative then suggested that the doctor prescribe Zyprexa.

"I inquired what Zyprexa was indicated for she then indicated that many physicians might prescribe an antipsychotic for this patient. I then asked for her package insert and read to her that her product was indicated for schizophrenia and bipolar mania -- neither of which the presented patient had been diagnosed with," the doctor wrote.

He added that he had never contacted the F.D.A. before but was "genuinely concerned about the promotion of this powerful drug to my peer community of primary care physicians outside of its approved and intended purpose."

Tara Ryker, a spokeswoman for Lilly, said the company no longer uses "Martha" or "Donna" in its marketing. "We are constantly developing new promotional materials and new profiles," she said.

The Zyprexa documents were provided to The Times by James B. Gottstein, a lawyer who represents mentally ill patients and has sued the state of Alaska over its efforts to force patients to take psychiatric medicines against their will.

Mr. Gottstein said yesterday that the information in the documents should be available to patients and doctors, as well as judges who oversee the hearings that are required before people can be forced to take psychiatric drugs.

"The courts should have this information before they order this stuff injected into people's unwilling bodies," Mr. Gottstein said.

Lilly originally provided the documents, under seal, to plaintiffs lawyers who sued the company claiming their clients developed diabetes from taking Zyprexa. Last year, Lilly agreed to pay \$700 million to settle about 8,000 of the claims, but thousands more are pending. Mr. Gottstein, who is not subject to the confidentiality agreement that covers the product liability suits, subpoenaed the documents in early December from a person involved in the suits.

The "Viva Zyprexa" documents also provide color about Lilly's efforts to motivate its sales force as they marketed Zyprexa -- whose generic name is olanzapine -- to primary care doctors.

At the 2001 meeting in Dallas with Zyprexa sales representatives, Mr. Bandick praised 16 representatives by name for the number of prescriptions they had convinced doctors to write, according to a script prepared in advance of the meeting. More than 100 other representatives had convinced doctors to write at least 16 extra prescriptions and thus

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"maxed out on a pretty sweet incentive," he said.

"Olanzapine is the molecule that keeps on giving," Mr. Bandick said.

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GRAPHIC: Photo: Zyprexa, an Eli Lilly drug, is approved to treat schizophrenia. (Photo by J.B. Reed/Bloomberg News)(pg. A26)

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